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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/807,462 | 07/19/2001 | Beth A. Burnside | 550750 | 7386 |

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/04/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,462

Applicant(s)

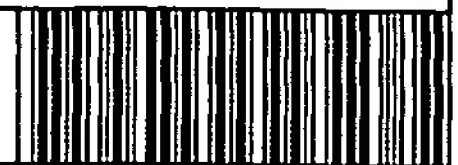
Burnside et al

Examiner

R.S. Travers J.D., Ph.D.

Art Unit

1617



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 13, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21, 27, 35, and 42-102 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 27, 35, and 42-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

Art Unit:

The amendment filed December 13, 2002 has been received and entered into the file.

Applicant's arguments filed December 13, 2002 have been fully considered but they are not deemed to be persuasive.

Claims 19-21, 27, 35, and 42-102 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21 27, 35, 42, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants fail to set forth in sufficient detail that information required to produce those delayed release dosage forms herein claimed; as set forth in the office action filed June 24, 2002.

Claims 27, 35, 42, 45 46, 47-66 and 76-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants fail to set forth in sufficient detail that information required to produce those delayed

Art Unit:

release dosage forms providing specific medicament levels as herein claimed; as set forth in the office action filed June 24, 2002.

Claims 44 and 83 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 83 are rendered indefinite by being dependant on canceled claim 32.

Claims 19-21, 27, 35, 42, 45 and 46 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants fail to set forth in sufficient detail that subject matter of the envisioned invention and thereby failing to clearly set forth the metes and bounds of the patent protection desired; as set forth in the office action filed June 24, 2002.

Claims 47-73, 77-78, 85-102 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47-73, 77-78 and 85-102 are rendered indefinite by the phrase "substantially the same shape of that of figure 7, adjusted proportionally for said dosage amounts" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Examples of what medicaments, excipients, or in which

Art Unit:

amounts would provide "substantially the same shape of that of figure 7, adjusted proportionally for said dosage amounts" are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of compounds, excipients, or amounts of said ingredients that could provide "substantially the same shape of that of figure 7, adjusted proportionally for said dosage amounts". Applicant's phrase fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 19-21, 27, 47-80 and 93-100 are rejected under 35 U.S.C. § 103 as being unpatentable over US 5,312,388 as set forth in the office action filed June 24, 2002 (paragraph 16).

Art Unit:

Claims 81-92 and 01-102 are rejected under 35 U.S.C. § 103 as being unpatentable over US 5,312,388 in combination with US 5,885,998 as set forth in the office action filed June 24, 2002 (paragraph 17).

RESPONSE TO ARGUMENTS

Claims 19-21 27, 35, 42, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants fail to set forth in sufficient detail that information required to produce those delayed release dosage forms herein claimed; as set forth in the office action filed June 24, 2002.

Claims 27, 35, 42, 45 46, 47-66 and 76-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants fail to set forth in sufficient detail that information required to produce those delayed release dosage forms providing specific medicament levels as herein claimed; as set forth in the office action filed June 24, 2002.

Examiner finds the presented rebuttal arguments unconvincing. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein

Art Unit:

employed: "the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Examiner notes the data set forth in figure 7 provides data for the concentration levels of one (1) medicament in vivo. In the instant case, the claims read on employing more than one medicament, yet no guidance is provided for those situations where

Art Unit:

multiple medication levels are envisioned. Simply stated, the instant claims are just an invitation to experiment.

Claims 19-21, 27, 47-80 and 93-100 are rejected under 35 U.S.C. § 103 as being unpatentable over US 5,312,388 as set forth in the office action filed June 24, 2002 (paragraph 16).

Claims 81-92 and 101-102 are rejected under 35 U.S.C. § 103 as being unpatentable over US 5,312,388 in combination with US 5,885,998 as set forth in the office action filed June 24, 2002 (paragraph 17).

Applicants' presented rebuttal arguments are unconvincing. The instant rejected claims are directed to a compositions of matter, providing a controlled release profile. US 338 provides abundant information directing the skilled artisan to the instant compounds; and various sustained release profiles, to include those herein claimed (see columns 9-15, esp column 9, after line 50). Examiner notes the instant claims fail to recite any limitation distinguishing the two pulse curve herein envisioned from that "multi-pulse" guidance provided by the cited prior art of record. That data presented in figure 7, set forth a multi-phase curve with a shoulder, thus, not distinguishable from other similar multi-phase curves.

Applicants constructively aver unexpected benefits residing in the claimed subject matter, yet fail to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA

Art Unit:

1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant compounds, carriers and excipients are not specifically recited concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

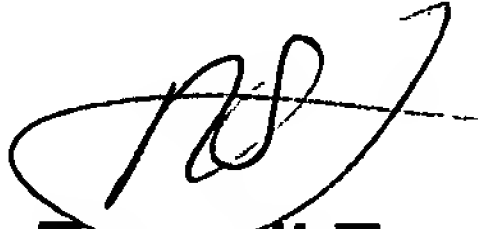
Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

Art Unit:

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
Art Unit 1617